



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,348	01/25/2002	Ronald M. Burch	200.1079CON4	8332

7590 06/14/2005

Davidson, Davidson & Kappel, LLC
14th Floor
485 Seventh Avenue
New York, NY 10018

EXAMINER

CELSA, BENNETT M

ART UNIT	PAPER NUMBER
----------	--------------

1639

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/056,348

Applicant(s)

BURCH ET AL.

Examiner

Bennett Celsa

Art Unit

1639

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 38,39 and 46-50.

Claim(s) withdrawn from consideration: _____

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: of reasons of record and for reasons herein.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____

Bennett Celsa
Primary Examiner
Art Unit: 1639

Advisory Action Cont.

Applicant's After-Final Response dated 4/20/05 is acknowledged.

The Prior Art Rejections of Record Are Retained For The Reasons of Record.

Applicant's newly raised arguments to the extent not previously addressed hereby follow.

Discussion

Applicant's arguments directed to the rejections of record were considered but deemed nonpersuasive for the following reasons.

Applicant argues that although Baker '936 teaches an analgesic composition comprising ibuprofen (e.g. NSAID) with a narcotic analgesic (e.g. oxycodone) the Baker patent reference does not teach NSAID's in general. In fact applicant asserts that Baker teaches away from utilizing NSAID's other than ibuprofen.

These arguments were considered but deemed nonpersuasive.

Applicant's interpretation of the Baker patent reference fails to consider the Baker patent teaching as a whole to one of ordinary skill in the art:

"The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998).

Accordingly, the Baker teaching includes Baker's entire specification and claims, inclusive of Baker's summary of the state of the prior art as illustrated in the "The Background of the

Art Unit: 1639

Invention" (col. 1-2). In this respect, Baker '936 (col. 1-2) cites numerous prior art references starting with Sunshine et al. for the premise of making analgesic compositions by combining NSAID's with narcotic analgesic (distinguished by merely additive analgesic effect) as well as other NSAIDS's (e.g. acetaminophen etc) with various narcotic analgesics, most notably oxycodone. Baker's invention (e.g. following the summary) is distinguished from the prior art by selecting compositions comprising ibuprofen as the NSAID in combination with narcotic analgesics (including oxycodone) in synergistically effective amounts while reducing the amounts of the narcotic analgesic thus addressing the problem of addiction (pointed to at the end of the "Background of the Invention").

In light of the "Background of the Invention" and lack of any evidence that substitution with a different NSAID would render pain treatment inoperative applicant's teaching away argument is not understood. At most, the selection of a different NSAID may lead to less than synergistic pain relief (e.g. additive) and as such may be "less preferred". In this regard, however, it is noted that:

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). See also MPEP 2121.04.

Additionally, even assuming arguendo that applicant's interpretation of the Baker reference is correct and Baker is limited to combining ibuprofen with oxycodone, applicant's argument does not overcome obviousness since applicant's arguments are directed against the Baker reference individually. In this respect, one cannot show nonobviousness by attacking

Art Unit: 1639

references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). IN other words the obviousness rejection provides ample motivation in the recited secondary reference(s) to substitute the presently claimed NSAID for ibuprofen.

In this regard, applicant argues that selecting from the secondary reference(s) the presently claimed NSAID amounts to “picking and choosing”.

This argument lacks merit since the secondary reference provides a rather small selection of NSAID’s and additionally provides motivation to select the presently claimed NSAID as pointed out in the obviousness rejection (s) of record.

Finally, applicant’s argument regarding the inapplicability of *In re Kerkhoven* in the present instance lacks merit, since applicant’s “teaching away” argument does not apply to the references of record.

Accordingly, for the reasons recited above and for the reasons already of record, the obviousness rejections of record are hereby maintained.

Art Unit: 1639

Future Correspondences

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639



BC
May 27, 2005